REMARKS

In the Office Action dated November 20, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §§121 and 372, alleging that the subject matter defined by the claims of the present invention represents **three** separate and distinct inventions as follows:

Group I, Claims 1-3, 22-24, drawn to the compounds of Formula I where X is phenyl or naphthalene, the compositions and one method of use of the compounds from Claims 4-21;

Group II, Claims 1-3, 22-24, drawn to the compounds Formula I wherein X is the third formula in Claim 1, the compositions and one method of use of the compounds from Claims 4-21;

Group III, Claims 4-21, drawn to the methods of using the compounds.

In addition, the Office Action has requested applicants to elect a species.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of **Group I, Claims 1-3 and 22-24.** In addition, they elect, with traverse, the use of the elected compounds for inhibiting the aggregation of amyloid proteins to form amyloid deposits. Finally, applicants elect, with traverse, the species of Example 26.

Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In fact, applicants submit that Groups I-III are not independent. MPEP §802.01 defines independent as follows:

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design operation or effect.

The subject matter in Group I-III are all drawn to compounds of Formula I, or the use thereof and a pharmaceutical composition containing these compounds. Thus, because these groups of claims are connected in design, operation or effect, the claims are not independent. Thus the claims which the Office Action has grouped separately are not independent and distinct, so as to justify the Restriction Requirement.

Moreover, contrary to the allegations in the Office Action the claimed subject matter complies with the unity of invention. Since the present application is based on a PCT application, and since the subject matter relates to one general inventive concept, as explained hereinbelow, the Restriction imposed by the United States Patent and Trademark Office is improper.

The claimed subject matter relates to compounds which inhibits amyloid protein aggregation. By inhibiting such aggregation the compounds of the present invention are useful for treating various diseases caused or mediated or resulting from the presence of amyloid deposits and are administered to patients suffering from these deposits. Moreover, by virtue of the ability of the compounds to inhibit amyloid accumulation, as part of its mechanism of action, the compounds of the present invention associates with amyloid protein, and therefore labeled compounds of the compounds of the present invention are useful for diagnosing amyloid deposits in the brain. Thus, the use of labeled compounds provide valuable information for diagnosis of patients and in assessing the extent of the growth of the amyloid deposits.

The Office Action alleges, without evidence, that Groups I and II do not relate to a single inventive concept because the subject matter reads on or is rendered obvious by the prior art. However, the Office Action has the burden of establishing the lack of unity of invention; the Office Action has not met its burden because it has made only conclusions regarding the prior art without providing the supporting rationale and documentation. Moreover, even if true, the link above is still maintained. Thus, Groups I and II have a unity of invention.

Further, in support of the Restriction Requirement, the Office Action alleges that Groups I and II and III are related as product and process of use. The Office Action alleges that the present invention has more than one use. However, the various uses stem from the ability of the compounds of Formula I to inhibit amyloid aggregation. Thus, the various uses are merely applications of one inventive concept.

Thus, applicants respectfully submit that these groups are all different aspects of a single invention. Consequently, it is improper to impose a Restriction Requirement, since the claimed subject matter defines a single inventive concept.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants further submit that the interdependence of Groups I-III is confirmed -- indeed, it is mandated-- by virtue of the fact that 35 U.S.C. §112 compels disclosure of all aspects of the invention in the one application which applicants have filed. For example, an application claiming a product useful for inhibiting amyloid aggregation must disclose inter alia, the various uses that flow therefrom. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first paragraph. Consequently, it is clear that aspects of a given invention, such as a product and its uses and are necessarily interdependent, not independent, from each other.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

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> therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

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Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

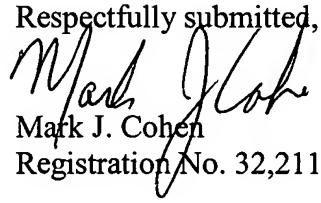
It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q.

2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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